

SOUTH AMERICAN GELATIN MANUFACTURERS ASSOCIATION – S A G M A

Comments on Advance Notice of Proposed Rulemaking

Federal Measures to Mitigate BSE Risks: Considerations for Further Action

**Food Safety and Inspection Service
U.S. Department of Agriculture
Docket No. 04-021ANPR**

September 10, 2004

The South American Gelatin Manufacturers Association (SAGMA) is a trade association whose members include all, except one, of the producers of edible, pharmaceutical and technical gelatin in the South America¹. SAGMA members sell edible gelatin directly to hundreds of food manufacturers and distributors in the South America and a variety of export markets. SAGMA members also sell gelatin directly to soft gel and hard shell capsule producers, primarily for use in dietary supplements. SAGMA members export gelatin to many countries around the world for use in dietary supplement capsules.

The SAGMA member companies are totally committed to ensuring that all gelatin is safe for human consumption. Over the years SAGMA has supported all regulatory agencies in their implementation of appropriate measures to protect the public from health risks associated with BSE and to prevent the spread of the disease in South America cattle.

FSIS, APHIS and FDA are considering additional safeguards to protect the public and U.S. cattle from BSE risks based on recommendations of an international review team convened by the Secretary of Agriculture. The members of SAGMA support this effort. FSIS has posed several questions in their ANPPR and solicited public comments. A number of the questions address the equivalency of regulatory schemes among relevant countries. Specifically, FSIS is requesting comment on whether it should consider a country's BSE risk while assessing the equivalence of a country's sanitary measures to prevent human exposure to the BSE agent to those required by the U.S. SAGMA has chosen to comment on this issue as it has great implication not only on the safety of the food supply, but also on the flow of international trade.

SAGMA submits the following specific comments in response to FSIS questions 34-36.

¹ SAGMA members include: Gelco , Colombia ;Progel, Colombia; Gelnex, Brasil; Gelita South America, Brasil; PB Leiner, Argentina; Rebièri, Brasil; Rousselot, Argentina.

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34. Should FSIS provide an exemption for “BSE free” countries or countries with some other low-risk BSE designation?

Conceptually, BSE free countries and countries with low-risk BSE designation should be permitted to provide cattle materials (even when they contain prohibited materials) with sufficiently low BSE risk that importation of such materials should be considered equivalent to the sanitary measures in place in the U.S. as long as their status is corroborated by the USDA and the spontaneous etiology of BSE is not proven. This is consistent with OIE standards that do not require the removal of SRMs for BSE free, provisionally BSE free countries, or minimal BSE risk countries that trade in commodities from cattle including: gelatine and collagen from hides and skins, gelatin and collagen from bone, dicalcium phosphate and hides and skins.

35. If FSIS were to exempt “BSE free” countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country’s BSE status?

SAGMA believes that in determining a country’s BSE status FSIS should apply both, the existing “European Commission’s Scientific Steering Geographical BSE Risk Classification” and the OIE standards that contain criteria for establishing the BSE risk status of a country or zone. SAGMA strongly supports world-wide harmonization of standards – standards which deal both with the sourcing of raw materials and processing of these materials – to ensure consistent safety of products traded globally. Again, we would only support this approach to the extent that other countries would also adopt the same standards.

36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

While SAGMA supports the use of the “European Commission’s Scientific Steering Geographical BSE Risk Classification” and the OIE standards in assessing the BSE status of countries, SAGMA strongly believes that the evaluation of any given country should be done by FSIS. Assessment of country must be supported by first-hand inspection of the country against those standards. Therefore, a thorough inspection of BSE-related practices in that country by FSIS should be robust and equivalent to the oversight that FSIS extends to their evaluation of those same types of practices in the United States.

Thank you in advance for your consideration of the SAGMA comments.

Sincerely,

Hugo Armando Burdman
President
SAGMA